

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No.: PTQ-0027

Inventors: Van Eyk et al.

Serial No.: 09/115,589

Filing Date: July 15, 1998

Examiner: Borgeest, Christina M.

Customer No.: 26259

Group Art Unit: 1649

Confirmation No.: 1553

Title: Methods of Diagnosing Muscle Damage

DECLARATION BY JEREMY A. SIMPSON

I, Jeremy A. Simpson, hereby declare:

1. I am a co-inventor on the above referenced patent application.
2. I have reviewed the Office Action mailed March 27, 2007.
3. As shown in Figures 1 and 2, attached hereto, we have detected proteolytic fragments of fsTnI in serum of human patients suffering from various skeletal muscle disorders including trauma, seizures, and drug-induced rhabdomyolysis.

Figure 1A shows representative Western blots of serial samples from 5 patients probed for fsTnI. For this experiment, the first blood sample on hospital admission is considered time 0.

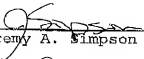
Western blots of Figure 1B show that while presence and number of proteolytic fragments varied between patients, the levels were unrelated to creatinine kinase concentrations.

Figure 2 shows Western blots of serial serum samples from a patient suffering from skeletal muscle damage resulting from seizures.

The proteolytic fragments were detected using anti-fsTnI mAb F1-32 and F1-23, commercially available from Spectral Diagnostics and SI-1, commercially available from Hytest. The proteolytic fragments were detected in serum via SDS-PAGE and Western Blot Analysis similarly to the procedures set forth at pages 28-30 of our patent application. Any modifications in procedure were routine changes due to differences in sample type.

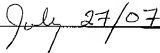
4. As shown in Figures 1 and 2 multiple proteolytic fragments were detected in the molecular weight range of 20 to 26.6 kDa. In fact as many as 7 proteolytic fragments were detected for fsTnI.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.



Jeremy A. Simpson

Date



July 27/07

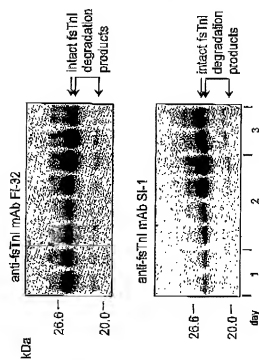


Figure 2

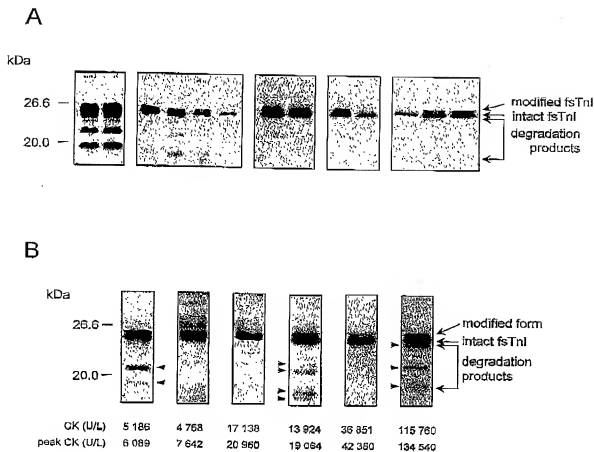


Figure 1